

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference RLL - 374WO	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/IB2004/001003	International filing date (day/month/year) 01/04/2004	(Earliest) Priority Date (day/month/year) 01/04/2003
Applicant RANBAXY LABORATORIES LIMITED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 7 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☒ **Certain claims were found unsearchable** (See Box II).

3. ☒ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regards to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. _____

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

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Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
Although claim 25 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Although claim 25 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-22

Process for producing substantially pure pravastatin, the process comprising culturing microorganisms under conditions capable of converting compactin to pravastatin by maintaining a concentration of compactin not less than 300 $\mu\text{g/ml}$ during the process.

2. claims: 23-25

Substantially pure pravastatin, a pharmaceutical composition comprising said pravastatin and a method of treating hypercholesterolemia comprising administering said pharmaceutical composition.

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C12P7/62 C12P17/06 C07C67/00 A61K31/215
//(C12P7/62,C12R1:465)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12P C07C A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, BIOSIS, WPI Data, PAJ, FSTA

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98/45410 A (YUNGJIN PHARMACEUTICAL IND CO ; KIM JI YOON (KR); LEE JOO KYUNG (KR);) 15 October 1998 (1998-10-15) page 9, line 15 - line 27; claims 2,4	1-22
P,X	PARK JOO-WOONG ET AL: "Bioconversion of compactin into pravastatin by Streptomyces sp." BIOTECHNOLOGY LETTERS, vol. 25, no. 21, November 2003 (2003-11), pages 1827-1831, XP008033522 ISSN: 0141-5492 the whole document	1-22

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

18 October 2004

Date of mailing of the international search report

01 11. 2004

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International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	HOSOBUCHI M ET AL: "APPLICATION OF COMPUTER TO MONITORING AND CONTROL OF FERMENTATION PROCESS: MICROBIAL CONVERSION OF ML-236B NA TO PRAVASTATIN" BIOTECHNOLOGY AND BIOENGINEERING, INTERSCIENCE PUBLISHERS, LONDON, GB, vol. 42, no. 7, 1993, pages 815-820, XP002036625 ISSN: 0006-3592 cited in the application the whole document	1-22
A	US 2002/081675 A1 (HORVATH GYULA ET AL) 27 June 2002 (2002-06-27) cited in the application	1-22
X	page 1 - page 2 page 5, paragraph 36 page 6, paragraph 44; example 2	23-25
A	US 2001/026934 A1 (YASHPHE JACOB ET AL) 4 October 2001 (2001-10-04) cited in the application the whole document	1-22
A	WO 00/17182 A (LEK TOVARNA FARMACEVTSKIH ; MILIVOJEVIC DUSAN (SI); BASTARDA ANDREJ (S) 30 March 2000 (2000-03-30)	1-22
X	abstract; claims 26-29; examples 1-5	23-25
X	GRAHEK R ET AL: "Chromatographic purification of some 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors" JOURNAL OF CHROMATOGRAPHY, ELSEVIER SCIENCE PUBLISHERS B.V. AMSTERDAM, NL, vol. 918, no. 2, 25 May 2001 (2001-05-25), pages 319-324, XP004239132 ISSN: 0021-9673 the whole document	23-25
X	DATABASE WPI Section Ch, Week 200250 Derwent Publications Ltd., London, GB; Class B05, AN 2002-471387 XP002301127 -& JP 2002 128739 A (SANKYO CO LTD) 9 May 2002 (2002-05-09) abstract	23-25

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Information on patent family members

International Application No

PCT/IB2004/001003

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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WO 0017182	A	30-03-2000	SI 20072 A AU 766630 B2 AU 5528499 A BG 105348 A CA 2343645 A1 CN 1318063 T EP 1114040 A1 HR 20010045 A1 HU 0102997 A2 WO 0017182 A1 JP 2002526486 T NZ 509582 A PL 345883 A1 SK 20022000 A3 US 2004138294 A1 US 6695969 B1	30-04-2000 23-10-2003 10-04-2000 30-11-2001 30-03-2000 17-10-2001 11-07-2001 31-12-2001 28-12-2001 30-03-2000 20-08-2002 31-10-2003 14-01-2002 06-08-2001 15-07-2004 24-02-2004
JP 2002128739	A	09-05-2002	JP 3463875 B2	05-11-2003